

AMENDMENTS TO THE CLAIMS

Please cancel claims 1-27, 62-88 and 112-134.

In this Preliminary Amendment A, no claims have been amended, claims 1-27, 62-88 and 112-134 have been canceled, and no new claims have been added.

Claims 1-27 are cancelled.

28. (original) A method for evaluating the stability of drug samples when exposed to various controlled conditions, the method comprising:

providing an array of drug samples;

simultaneously exposing a plurality of the drug samples to at least one controlled environmental condition for an exposure period;

simultaneously exposing the plurality of the drug samples to at least one controlled chemical condition for the exposure period; and

evaluating any change of the exposed drug samples.

29. (original) The method of claim 28, wherein the plurality of drug samples exposed to the controlled environmental condition and the plurality of drug compositions exposed to the chemical condition are drug candidates.

30. (original) The method of claim 28, wherein the plurality of drug samples are exposed in a chamber.

31. (original) The method of claim 28, wherein the controlled environmental exposure and the controlled chemical exposure occur simultaneously.

32. (original) The method of claim 28, wherein at least two of the drug samples of the array are different from each other.

33. (original) The method of claim 28, wherein at least one of the drug samples is exposed to

a first controlled chemical condition and at least one other drug sample is exposed to a second controlled chemical condition different from the first controlled chemical condition.

34. (original) The method of claim 28, wherein at least one of the drug samples is exposed to a first controlled environmental condition and at least one other drug sample is exposed to a second controlled environmental condition different from the first controlled environmental condition.
35. (original) The method of claim 28, wherein the drug samples are drug compositions.
36. (original) The method of claim 28, wherein at least one of the drug samples is a drug candidate and at least one of the drug samples is a drug composition.
37. (original) The method of claim 28, wherein the change in the exposed drug samples is a change in chemical composition of an active pharmaceutical ingredient.
38. (original) The method of claim 28, wherein the change in the exposed drug samples is a change in biological activity of the drug candidate.
39. (original) The method of claim 28, wherein the change in the exposed drug samples is a change in component compatibility.
40. (original) The method of claim 28, wherein a plurality of the drug samples of the array comprise a chemical selected from the group consisting of acids, bases, radicals and oxidizers.
41. (original) The method of claim 28, wherein the controlled environmental condition is selected from the group consisting of heat, humidity and light.
42. (original) The method of claim 28, wherein the drug samples of the array all have chemical or physical diversity.

43. (original) The method of claim 28, wherein the drug compositions of the array are the same.
44. (original) The method of claim 42, wherein at least one of the drug samples of the plurality of drug samples exposed to at least one controlled chemical condition is exposed to a first controlled chemical condition and at least one other drug sample of the plurality of drug samples exposed to at least one controlled chemical condition is exposed to a second controlled chemical condition different from the first controlled chemical condition.
45. (original) The method of claim 43, wherein at least one of the drug samples of the plurality of drug samples exposed to at least one environmental condition is exposed to a first controlled environmental condition and at least one other drug sample of the plurality of drug samples exposed to at least one controlled environmental condition is exposed to a second controlled environmental condition different from the first controlled environmental condition.
46. (original) The method of claim 42, wherein at least one of the drug samples of the plurality of drug samples exposed to at least one controlled environmental condition is exposed to a first controlled environmental condition and at least one other drug sample of the plurality of drug samples exposed to at least one controlled environmental condition is exposed to a second controlled environmental condition different from the first controlled environmental condition.
47. (original) The method of claim 45, wherein at least one of the drug samples of the plurality of drug samples exposed to at least one controlled chemical condition is exposed to a first controlled chemical condition and at least one other drug sample of the plurality

of drug samples exposed to at least one controlled chemical condition is exposed to a second controlled chemical condition different from the first controlled chemical condition.

48. (original) The method of claim 28, further comprising testing the exposed drug samples at least twice, wherein at least one of said tests is performed during the exposure period.
49. (original) The method of claim 48, wherein the testing is non-destructive.
50. (original) The method of claim 49, wherein the non-destructive test is selected from the group consisting of raman spectroscopy, X-ray diffraction, near infrared spectroscopy, dynamic light scattering and ultraviolet-visible spectroscopy.
51. (original) The method of claim 48, further comprising conducting a destructive test after the exposure period.
52. (original) The method of claim 48, wherein the testing is destructive.
53. (original) The method of claim 28, further comprising preparing the array of drug samples.
54. (original) The method of claim 28, further comprising daughtering the array into at least four additional arrays before exposure, resulting in at least a first array, a second array, a third array, a fourth array and a fifth array.
55. (original) The method of claim 54, wherein a plurality of the drug samples of the first array is exposed to a first controlled temperature condition, a plurality of the drug samples of the second array is exposed to a second controlled temperature condition different from the first temperature condition, a plurality of the drug samples of the third array is exposed to a first controlled humidity condition, a plurality of the drug samples of the fourth array is exposed to a second controlled humidity condition different from

the first humidity condition and a plurality of the drug samples of the fifth array is exposed to a controlled light condition.

56. (original) The method of claim 28, wherein the array is located on a common substrate.

57. (original) The method of claim 56, wherein each drug sample of the array is located on a spatially discrete region of the substrate.

58. (original) The method of claim 28, wherein the drug compositions of the array contain no more than 10 mg of active pharmaceutical ingredient.

59. (original) The method of claim 28, wherein a plurality of the drug samples of the array comprise an excipient selected from the group consisting of lubricants, surfactants, diluents, binders, fillers and disintegrants.

60. (original) The method of claim 28, wherein a plurality of the drug samples of the array comprise a chemical selected from the group consisting of acids, bases, radicals and oxidizers.

61. (original) The method of claim 28, further comprising placing the array of drug samples in a an exposure test chamber.

Claims 62-88 are cancelled.

89. (original) A method for evaluating the possible effects of a controlled exposure condition on a drug sample, the method comprising:
providing an array of drug samples on a single substrate;
exposing the array and the substrate to at least one controlled condition for an exposure period; and

evaluating the array of drug samples at least twice using one type of test with at least a portion of the exposure period being between the two tests to determine the effects of the exposure on the drug samples of the array, wherein the drug samples of the array remain on the substrate throughout the evaluation step.

90. (original) The method of claim 89, further comprising placing the array of drug samples in an environmental chamber prior to the exposing step.

91. (original) The method of claim 90, wherein the tests are conducted inside the environmental chamber.

92. (original) The method of claim 90, wherein the array of drug samples is removed from the environmental chamber for testing the drug compositions, and replaced in the environmental chamber after the tests.

93. (original) The method of claim 89, wherein the one type of test is a non-destructive test.

94. (original) The method of claim 93, wherein the non-destructive test is selected from the group consisting of raman spectroscopy, X-ray diffraction, near infrared spectroscopy, dynamic light scattering and ultraviolet-visible spectroscopy.

95. (original) The method of claim 93, further comprising evaluating the composition of the array of drug samples after the exposure period using at least one destructive test.

96. (original) The method of claim 95, wherein the destructive test is liquid chromatography.

97. (original) The method of claim 95, wherein the at least one destructive test is conducted in parallel.

98. (original) The method of claim 89, further comprising simultaneously exposing the array of drug samples to at least one controlled chemical condition.

99. (original) The method of claim 89, further comprising daughtering the array into at least

four additional arrays before exposure, resulting in at least a first array, a second array, a third array, a fourth array and a fifth array.

100. (original) The method of claim 98, wherein a plurality of the drug samples of the first array is exposed to a first controlled temperature condition, a plurality of the drug samples of the second array is exposed to a second controlled temperature condition different from the first controlled temperature condition, a plurality of the drug samples of the third array is exposed to a first controlled humidity condition, a plurality of the drug samples of the fourth array is exposed to a second controlled humidity condition different from the first controlled humidity condition and a plurality of the drug samples of the fifth array is exposed to a controlled light condition.

101. (original) The method of claim 100, wherein the at least one test is conducted in parallel.

102. (original) The method of claim 89, wherein the at least one test is conducted in parallel.

103. (original) A method of research for possible effects of exposure conditions on a drug sample or a component thereof, the method comprising:
providing an array of drug samples;
simultaneously exposing two samples of the array of drug samples to a set of controlled exposure conditions for a period of time, wherein the controlled exposure conditions vary across the array;
testing the exposed samples; and
determining if there has been any change in the exposed drug samples.

104. (original) The method of claim 103, further comprising placing the array of drug

samples in an enclosure prior to exposure.

105. (original) The method of claim 103, wherein the controlled conditions are environmental conditions selected from the group consisting of light, temperature and humidity.
106. (original) The method of claim 103, wherein the array of drug samples are located on a common substrate.
107. (original) The method of claim 103, wherein the method is software integrated.
108. (original) The method of claim 103, wherein the testing is non-destructive.
109. (original) The method of claim 103, wherein the testing is destructive.
110. (original) The method of claim 103, wherein the testing comprises a non-destructive test conducted at least twice on the exposed samples during the period of time, and a destructive test conducted on the exposed samples after the period of time.
111. (original) The method of claim 110, wherein the exposed samples are tested in parallel.

Claims 112-134 are cancelled.